

REMARKS/ARGUMENTS

Applicants have carefully studied the Non-Final Office Action mailed on March 23, 2005 and gratefully acknowledge the Examiner's acceptance of the § 1.131 Declaration and allowance of claims 1, 5-7, 33-34, and 39. As the Examiner has also rejoined previously withdrawn claims 12-27, all pending claims are currently under direct examination. The Applicants now present the following arguments and remarks, which are intended to respond fully to all points of rejection raised by the Examiner and accordingly, to place all pending claims in condition for allowance.

Status of Claims

Claims 1-7, 12-27, 33-35, and 39-58 are presently pending.

Claims 1, 5-7, 33-34, and 39 have been allowed.

Claims 2-3, 12-14, 16-18, 20, 22-23, 26-27, 35, 40-41 and 47 have been amended.

No new matter has been added.

Claims 2-4, 12-27, 35, and 40-58 stand rejected.

Rejections under 35 U.S.C. § 112, First Paragraph***Claims 2-4 and 40-46***

In paragraph 7 of the Office Action, the Examiner has rejected claims 2-4 and 40-46 as failing to comply with the enablement requirement. In particular, the Examiner has rejected each claim's requirement of an "isolated nucleic acid" that "is a gene," asserting that the two terms are mutually exclusive of each other.

In response, Applicants have removed the phrase “a gene,” as implicitly suggested by the Examiner, to simplify the terminology. The claims as amended are of the same scope as prior to the amendment.¹

Claim 35

In paragraph 8 of the Office Action, the Examiner has rejected claim 35 as failing to comply with the enablement requirement. Applicants have amended this claim to eliminate reference to a pharmaceutical composition. As amended, the claim recites “[a] vector comprising the nucleic acid of claim 1.”

On the basis of these changes and remarks, Applicants respectfully submit that the grounds for rejection under this provision have been overcome. Accordingly, the rejections should be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 2-4, 12-27 and 40-58

In paragraph 9 of the Office Action, the Examiner has rejected claims 2-4, 12-27, and 40-58 as being indefinite. Specifically, the Examiner has raised three grounds of rejection, which are

¹ Applicants do not necessarily agree that the terms “isolated nucleic acid” and “gene” are not mutually exclusive; the molecular biological arts readily recognize an “isolated nucleic acid” that “is a gene.” A search of the Pubmed database reveals over two hundred articles describing an “isolated gene.” The term “gene,” however, is not necessary to either clarify or scope of the claims.

addressed in turn (the parenthetical designations refer to the corresponding paragraphs in the Office Action):

(9.1) The Examiner has rejected claims 2-4, 12-27, and 40-58 based on the assertion that the limitation “mutation” does not have a point of reference. In response, the Applicants have amended the claims so that the point of reference for “mutation” is “relative to SEQ ID NO:1 or SEQ ID NO:2.”

The Examiner has also included claims 3, 14, 18, 22, and 27 in this rejection, asserting that the recited sequence identifiers are contained within parentheses, making it unclear if they are limiting or only exemplary. In response, Applicants note that the sequence identifiers refer to either the wild-type genomic sequence (SEQ ID NO: 1) or the wild-type cDNA sequence (SEQ ID NO:2). The references to SEQ ID NOs are recited to show the numerical position of the recited mutation in the specified genomic (SEQ ID NO: 1) or cDNA (SEQ ID NO:2) sequence. To make this clear, Applicants have removed the parentheses from the identifiers and added the linker “of.”

(9.2) The Examiner has rejected claims 23-27 as incomplete because they are kit claims that only recite a single component. In response, Applicants have added a second component: “a means for detecting binding of the oligonucleotide to the nucleic acid.”

(9.3) The Examiner has rejected claims 12-22 and 47-58 as indefinite, based on the assertion that they do not set forth any active, positive steps involved in the method or process. making it unclear what method or process is intended. In response, Applicant have amended these claims to include additional active steps that do not affect the scope of the claims, but address the Examiner’s concerns with respect to clarity.

On the basis of these changes and remarks, Applicants respectfully submit that the grounds for rejection under this provision have been overcome, and that accordingly, the rejections should be withdrawn.

Rejections under 35 U.S.C. § 101

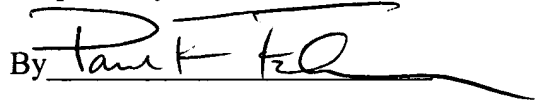
The Examiner has rejected the claims 12-19 and 47-52 based on the contention that the claimed recitation of use results in an improper definition of a process. As these claims have been amended as above, the grounds for this rejection are moot. Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above amendments and remarks, Applicants believe that each of the presently pending claims in this application is in condition for allowance. Accordingly, Applicants respectfully request that the Examiner enter the foregoing amendments and remarks in the file history, and pass this application to issue.

Dated: June 23, 2005

Respectfully submitted,

By 

Paul F. Fehlner, Ph.D.

Registration No.: 35,135

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorney For Applicant